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**14. ABSTRACT**

The purpose of the research supported by this award is to conduct a Phase II clinical trial (study) of an adenovirus/PSA (Ad/PSA) vaccine for the treatment of prostate cancer. Two protocols have been used in the trial: #1 - Phase II study of Adenovirus/PSA vaccine in men with recurrent prostate cancer after local therapy; and #2 - Phase II study of Adenovirus/PSA vaccine in men with hormone refractory prostate cancer. In the first protocol men with newly recurrent prostate cancer were randomized to one of two arms of the study. Patients in Arm A received the Ad/PSA vaccine only; three injections spaced 30 days apart. Patients in Arm B received androgen deprivation therapy (ADT) followed at day 14 by the Ad/PSA vaccine, again with three injections. In the second protocol men with hormone refractory prostate cancer were injected with the vaccine only, three injections 30 days apart. The patients were followed for toxicity, the development of anti-PSA immune responses, and evidence of a clinical effect of the vaccination. The latter includes changes in serum PSA and prostatic acid phosphatase (PAP) levels and in the PSA doubling times (PSADT). Patients in protocol #2 also have CT and bone scans to monitor.

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**INTRODUCTION**

The purpose of the research supported by this award is to conduct a Phase II clinical trial (Study) of an adenovirus/PSA (Ad/PSA) vaccine for the treatment of prostate cancer. Two protocols are being used in the trial: #1 – *Phase II study of adenovirus/PSA vaccine in men with recurrent prostate cancer after local therapy,* and #2 – *Phase II study of adenovirus/PSA vaccine in men with hormone refractory prostate cancer*. In the first protocol men with recent documentation of recurrent prostate cancer are randomized to one of two arms of the study. Patients in Arm A receive the Ad/PSA vaccine only; three injections spaced 30 days apart. Patients in Arm B will receive androgen deprivation therapy (ADT) followed at day 14 by the first of three Ad/PSA injections. In the second protocol men with hormone refractory prostate cancer are injected with the vaccine only, three injections 30 days apart. The patients are followed for toxicity, the development of anti-PSA immune responses, and evidence of a clinical effect of the vaccination. The latter includes changes in serum PSA and prostatic acid phosphatase (PAP), and the PSA doubling times (PSADT). Patients in protocol #2 also have CT and bone scans to monitor their prostate cancer.

**BODY:**

The first year of the award, from April 1, 2007 through March 31, 2008, was occupied by negotiations and submissions of documents to the DOD's PCRP, including the Human Subjects Research Review Board (HSRRB), the FDA, NIH's Recombinant DNA Review Committee (RAC), the University of Iowa IRB, the Iowa City VA Medical Center IRB, and the Iowa City VA Medical Center Research and Development Committee. During the subsequent years we have been recruiting patients, evaluating their eligibility, screening them for adherence to our entry criteria, vaccinating them and following their clinical and immunological responses according to the schedule described in the protocols.

**Recruitment –** Patients were initially recruited into the trial from the Urology Clinic in the University of Iowa Hospitals and Clinics (UIHC) and the Urology Service at the adjacent Iowa City VA Medical Center. Additional recruitment was through (1) Referrals from private practice physicians (urologists, medical oncologists, and radiation oncologists) following the mailing of a letter sent to these physicians in the State of Iowa and bordering regions of Nebraska, Missouri, Illinois, Minnesota, and Wisconsin. A follow-up letter to the same physician mailing list was sent in 2009, and additional letters have been sent following protocol modifications in 2010, during the 2010 holiday season, in July 2011, and most recently in March 2012. Referrals from academic physicians (urologists, medical oncologists, and radiation oncologists) following a mailing of a letter sent to academic and VA medical centers in the same geographic areas covered by the letters to the private practice physicians. Follow-up letters were sent early in 2010, again at the holiday season of the same year, July 2011, and March 2012. We also sent letters to family practice physicians in Johnson County Iowa (Iowa City is located in this county), and surrounding counties in a 50 mile radius from Iowa City requesting referrals. (2) The trial is listed on www.clinicaltrials.gov website. (3) Presentation of results from the Phase II trial of the Ad/PSA vaccine at the annual meeting of the American Association for Cancer Research (AACR) in 2010 and 2012, the American Society of Clinical Oncology (ASCO), the ASCO Genitourinary Malignancies Conference, the Fall Symposium of the Society for Basic Urologic Research (SBUR), and the North Central Section of the American Urologic Association (AUA). (4) Talks to prostate cancer survivor support groups in at the University of Iowa, Mercy Medical Center in Cedar Rapids, IA, and the Us TOO chapter in Rock Island, IL, and at Us Too chapter and medical faculty at the Marshfield Clinic, Marshfield, Wisconsin. (4) Publication in the University of Iowa Hospitals and Clinics' *"Pacemaker"* magazine with a "Q & A" with me about

the trial. (5) Publication of the trial in the University of Iowa Hospitals and Clinics' *"UI Consult."* This is a communication that is mailed to all physicians on a very large mailing list. The publication reaches a larger group of physicians than did our list for the letters, particularly family practice and general practice physicians. (6) Publication of the trial in the University of Iowa Hospitals and Clinics' *"Medicine"* magazine. The PI was interviewed and photographed for the article. Other participants in the article are the Co-PI of the award Dr. Richard Williams and one of our trial patients. (7) Publication in the Department of Veterans Affairs "*VA Currents,"* that is sent via the internet and hard copy to VA Medical Centers. (8) An "Eblast" to the membership email list of Us TOO International (attached).

As of April 30, 2012, we have consented and screened a total of 87 patients for eligibility into the two protocols in the study. Forty-three patients were consented for Protocol #1, 33 from the state of Iowa and 10 from outside the state. Of these 43, 28 were deemed eligible based upon our inclusion and exclusion criteria; 16 were randomized to Arm A, vaccine only, and 12 were randomized to Arm B, androgen deprivation therapy (ADT) plus vaccine. Eleven subjects failed screening; 1 patient for seminal vesicle involvement at original pathology, 3 with positive CT scans, 1 had an infection at the time of screening, 1 had an ineligible screening bilirubin, 3 had decreased or fluctuating PSA values, and 1 had a PSADT of < 6 months. One patient had castrate levels of testosterone when evaluated further. Two patients previously reported as screen failures became eligible and were treated. These subjects were not counted twice, even though consented and screened at different time points. Four patients were consented but screening was delayed due to a reduction in their PSAs; (one of these patients has now withdrawn consent). Screening will resume when appropriate by PSA eligibility criteria.

Forty-four patients were consented for Protocol #2, 29 from Iowa and 15 from outside the state. Of these 44, 25 patients were deemed eligible and have been treated. Nineteen patients have failed screening; 6 failed for positive bone scans with exclusionary PSA values, 8 for positive CT scan, 1 for additional carcinoma, 2 for declining PSA, 1 for aggressive progression, and one subject died suddenly prior to study treatment. And one patient previously reported as a screen failure became eligible and was treated. This subject was not counted twice, even though consented and screened at different time points

We also have received inquiries by telephone or e-mail regarding 420 patients as a result of our registering the trial on the website www.clinicaltrials.gov and other recruitment efforts. During the last quarter, we received 23 inquiries; 12 of which were phone screen negative, and 11 which are pending further evaluation.

**Enrollment -** After all approvals were obtained patients enrolled during the current year are listed in Table 1.

**Table 1**
**Patients Enrolled from May 15, 2011 to May 14, 2012**

| Patient ID | Protocol | Arm | Information |
|---|---|---|---|
| APIIAHN-14 | 1 | A | Received all 3 vaccinations and completed visits to 9 months. |
| APIIAHN-15 | 1 | A | Received all 3 vaccinations and completed visits to 6 months. |
| APIIAHN-16 | 1 | A | Received all 3 vaccinations and completed visits to 90 days. |
| APIIAADT-09 | 1 | B | Received all 3 vaccinations and completed visits to 6 months. |
| APIIAADT-10 | 1 | B | Received all 3 vaccinations and completed visits to 74 days |

| | | | |
|---|---|---|---|
| APIIAADT-11 | 1 | B | Received 1 vaccination. |
| APIIB-19 | 2 | --- | Received all 3 vaccinations and completed visits to 12 months. |
| APIIB-20 | 2 | --- | Received all 3 vaccinations and completed visits to 9 months. |
| APIIB-21 | 2 | --- | Received all 3 vaccinations and completed visits to 9 months. |
| APIIB-22 | 2 | --- | Received all 3 vaccinations and completed visits to 9 months. |
| APIIB-23 | 2 | --- | Received 2 vaccinations and completed visits to 44 days. Deceased fro suspected pulmonary embolus. |
| APIIB-24 | 2 | --- | Received 2 vaccinations and completed visits to 44 days. |
| APIIB-25 | 2 | --- | Received 2 vaccinations and completed visits to 44 days. |
| APIIB-26 | 2 | --- | Received 2 vaccinations and completed visits to 44 days. |

**Adverse Events –** During the period of report there were two serious adverse events, one deemed likely unrelated to the vaccine and the other as possibly related. They are detailed below and previously reported to the DOD's HSRRB. All of the AEs for the patients enrolled in this grant year are identified in Table 2.

Patient in Protocol #2

The subject received his initial injection of the Ad/PSA vaccine on January 9, 2012 and his second injection on February 8, 2012. He had mild adverse events following the second injection (grade 1 fatigue and dry skin), and appeared to be doing well. He returned for his 44 day visit on February 20, 2012, with no complaints. He was due for his third and last injection on March 7, 2012, but called our Clinical Trial Coordinator Pamela Zehr to convey that he had a sinus infection. Our team decided to hold his study treatment until his infection had resolved. Further communication indicated that the patient had been diagnosed with pneumonia and was being treated with an antibiotic. Our next communication was from the son of the patient to Ms. Zehr reporting on his father's death.

We received reports from the Mary Greeley Medical Center, Ames, IA; McFarland Clinic, Ames, IA; and Ellsworth Municipal Hospital, Iowa Falls, IA; copies are de-identified for subject privacy, and are attached to this document. The text to follow is a summary of their findings.

The subject's first visit to the Mary Greeley Medical Center was on February 21, 2012 one day after his 44 day visit to the University of Iowa. His complaint was lower abdominal pain. Following a physical examination and abdomen/pelvis CT the patient was diagnosed with constipation and treated with manual disimpaction and enema. He was discharged home. Labs on that day were unremarkable other than a grade 1 ALT elevation.

On March 6$^{th}$, the subject was seen locally and diagnosed with a sinus infection (27 days after injection # 2) and antibiotics were prescribed.

On March 8$^{th}$, he reported feeling worse, and was evaluated by Jennifer Killion, MD at the McFarland Clinic. He reported flank and back pain in addition to worsening upper respiratory symptoms. Following physical examination, abdomen/pelvis CT, abdominal ultrasound, and chest x-ray, the patient was diagnosed with a left lower lobe infiltrate presumed to be pneumonia. The CT was performed without IV contrast and significant motion artifact was

noted. He was prescribed pain medication and antibiotic (Levaquin). On this visit he was again noted to have Grade 1 elevation of ALT and AST.

On March 10, 2012 the patient's wife brought him to the emergency room of the Ellsworth Municipal Hospital complaining that he "couldn't breathe." The patient thought he was having an asthma attack, but when examined he tested negative for an asthma attack as well as myocardial infarction. Almost immediately following the completion of the ECG the patient stopped breathing. Cardiopulmonary resuscitation was initiated and conducted with full support. After 45 minutes resuscitative efforts were terminated when the patient's pupils were fixed and dilated. The attending physician's estimate of the cause of death was "primary hypovolemia probably secondary to either pulmonary embolus or perhaps a ruptured major vessel such as a cardiac or thoracic aneurysm." No autopsy was performed.

The patient had no known previous medical history of coronary artery disease, vascular disease or thromboembolic disease. Pre-study CT abdomen and pelvis showed normal aorta. There were multiple tiny hypodensities in the liver which were felt to be non-specific and too small to characterize and overall unchanged over 4 years. There was bulbous prominence of the bile duct, of unclear significance. CXR had no infiltrates and liver function enzymes were normal.

In light of the fact that the death occurred while the patient was on protocol, between his second and third vaccinations, and in the absence of a proven alternative explanation, the study team considers this event possibly related to the vaccine. However, due to absence of an autopsy or other diagnostic testing, there is not enough information on this case to either support or refute the relationship with the investigational product, but the presentation would be most consistent with a presumably unrelated pulmonary embolus or aneurysmal rupture. Sudden death, pulmonary emboli, or aneurysmal ruptures have not been previously reported in the phase I-II experience with this product. There were no vaccine-related adverse events observed in the 32 patients enrolled and treated in the Phase I trial or in the patients thus far enrolled and treated in this Phase II trial.

Patient in Protocol #2

This will document the serious adverse event "cerebrovascular ischemia, grade 4" for patient APIIB-24. The patient received vaccine dose # 1 on March 20, 2012, and dose # 2 on April 17, 2012. Previous AE of transient fatigue was reported after injection #2. He had study labs drawn on May 1, 2012.

On Wednesday 5/2 about 6:00 am the patient had left facial numbness and thought he was too weak/unsteady to stand. Wife called 911 and he was brought to the University of Iowa Hospitals and Clinics Emergency Room. Brain CT without contrast was without evidence of acute abnormality. Labs were normal, and chest x-ray stable. MRI/MRA of brain with and without contrast revealed:

1. A small acute infarction involving the medial right pre- and postcentral gyrus.
2. Small subacute right PCA infarction.
3. Small vessel ischemic changes in several small old infarctions.

No evidence of aneurysm, stenosis or dissection on the MRA of the head or neck.
The facial numbness and weakness resolved in about 4 hours. Transesophageal echocardiogram showed no cardiac abnormality. Etiology is likely arthrosclerosis. Since the patient was already on ASA, Plavix was prescribed, and his statin dose was increased. He was discharged on May 4, 2012 neurologically stable. Physical therapy recommended rehabilitation,

so he was transferred to the inpatient acute rehabilitation center at St. Luke's Medical Center in Cedar Rapids, IA. The patient was discharged to his home on May 6, 2012.

This was a grade 4 event, "cerebrovascular ischemia", ***unlikely related*** to the study drug.

**Table 3**
**Adverse Events**

| Patient | Event | Grade | Vaccine Related |
|---|---|---|---|
| APIIAHN-14 | Uveitis | 2 | Unlikely |
| | Common cold | 1 | Unrelated |
| APIIAHN-15 | Symptomatic ketonuria | 1 | Unlikely |
| | Elevated leuko esterase | 2 | Unlikely |
| APIIAADT-09 | Hot flashes | 1 | Unrelated |
| | Flu | 2 | Possible |
| APIIAADT-10 | Headache | 1 | Possible |
| | Hot flashes | 1 | Unrelated |
| | Headache | 1 | Unlikely |
| APIIAADT-11 | Hot flashes | 1 | Unrelated |
| APIIB-21 | fatigue | 1 | Possible |
| APIIB-22 | Thigh pain | 1 | Possible |
| | Flu-like symptoms | 1 | Possible |
| | Melanoma resection | 1 | Unlikely |
| APIIB-23 | Fatigue | 1 | Possible |
| | Cracked lip/dry skin | 1 | Unlikely |
| | Sinus congestion | 1 | Possible |
| | Pneumonia | 2 | Possible |
| | Constipation increase | 3 | Unlikely |
| | Sudden death | 5 | Possible |
| APIIB-24 | fatigue | 1 | Possible |
| | CV ischemia | 4 | Unlikely |

**KEY RESEARCH ACCOMPLISHMENTS:**

For each patient we collected serum for future measurements of anti-PSA and anti-adenovirus antibodies, isolated lymphocytes from the peripheral blood for the measurement of anti-PSA and anti-adenovirus T cell responses, and measured serum levels of PSA and PAP.

**PSA Doubling Times (PSADT) –** One of the measurements used to follow the clinical pattern of prostate cancer before and after therapy is the change in doubling time of the serum PSA levels. We have evaluated the PSADT of the patients in this grant and presented in Table 3. The data on evaluable patients demonstrates that of these patients, on whom we had sufficient data to calculate both pre-vaccination and post-vaccination PSADT values, demonstrated that four or 60%, either had an increase in PSADT or a decline in total PSA and two or 40% had a decrease in the PSADT values. There are four enrolled patients that have too few post-vaccination PSA values to calculate their after treatment PSADT.

**Table 3**
**PSA Doubling Times (PSADT)**

| Patient | PSA at Start | Last PSADT | Percent Change |
|---|---|---|---|
| APIIAHN-14 | 1.95 | 10.84 | 71.79 |
| APIIAHN-15 | 3.54 | *PSA decline* | |
| APIIAHN-16 | 0.72 | Too few values to date | --- |
| APIIAADT-09 | 7.96 | NA* | --- |
| APIIAADT-10 | 10.09 | NA* | --- |
| APIIAADT-11 | 14.00 | NA* | --- |
| APIIB-19 | 12.68 | 3.93 | -69.01 |
| APIIB-20 | 25.81 | 17.81 | -33 |
| APIIB-21 | 1.93 | 6.05 | 213.47 |
| APIIB-22 | 3.60 | 16.18 | 349.44 |
| APIIB-23 | not avail | *PSA decline* | --- |
| APIIB-24 | 10.15 | too few | --- |
| APIIB-25 | 2.89 | too few | --- |
| APIIB-26 | 7.85 | too few | --- |

* - not applicable as PSA decline due to ADT.

**ELISPOT Analysis of Anti-PSA T Lymphocytes Immune Responses –** Since the primary arm of the immune response to tumor associated antigens has been documented as the T cell-mediated response, we examined the development of the responses over time after the initiation of vaccination. At each patient visit we obtained peripheral blood and isolated the lymphocytes by density gradient centrifugation. The majority of the lymphocytes were suspended in a cryopreservative solution and stored in liquid nitrogen for future analyses. At the end of the first 12 months following the initiation of therapy all of the samples for each patient will be thawed and an ELISPOT assay performed at one time. This is done to avoid inter-assay variability and will allow us to accurately compare the responses at each time point. When the lymphocyte yields were large such that we were able to cryopreserve sufficient numbers of cells for that single assay and have extra cells, we performed the ELISPOT assays on the freshly isolated cells. This has permitted us to obtain some preliminary measure of the anti-PSA T cells responses for the patients at the appropriate time points. However, the more definitive assays will be those performed on the stored cells after the 12 month time point. We have not been able to assay any of the patient's cells this grant year as we have been testing a variety of purified PSA products to use as the stimulating antigen in the assay. All of the patients' PBMC have been cryopreserved and will be analyzed as soon as the best PSA product has been identified.

**REPORTABLE OUTCOMES:**

Presentation of results from the Phase II trial of the Ad/PSA vaccine at the annual meetings of the American Association for Cancer Research (AACR) (2010 and 2012), the American Society of Clinical Oncology (ASCO), the ASCO Genitourinary Malignancies Conference, and the Fall Symposium of the Society for Basic Urologic Research (SBUR), the North Central Section of the American Urologic Association (AUA), and the DOD's IMPaCT meeting.

**CONCLUSION:**

Patients were enrolled in both protocols, vaccinated three times and followed by return visits to the University of Iowa Hospitals and Clinics and Iowa City VA Medical Center. No serious vaccine-related adverse events were reported for any of the patients. In the analysis of serum PSA and immune responses to PSA following the vaccinations, 60% of the patients demonstrated an increase in PSADT or decline to total PSA..

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# Research Study of a Vaccine for the Treatment of Recurrent Prostate Cancer

University of Iowa researchers are conducting Phase 2 research studies of a vaccine to treat men with recurrent prostate cancer. The studies are enrolling two patient populations into separate treatment protocols.

**Protocol #1** – men with the first evidence of recurrent disease following initial treatment as determined by a continued rise in PSA levels.

**Protocol #2** – men with castrate-resistant prostate cancer who have been treated by hormone therapy and continue to progress with or without evidence of the spread of the cancer.

Each person will be screened for eligibility to enter the study and, if accepted, will receive three vaccinations, each 30 days apart, followed by regular visits to the University of Iowa Hospitals and Clinics to follow their immune status, clinical laboratory analyses, and status of their recurrent disease.

Details can be found at clinicaltrials.gov, trials NCT00583752 and NCT00583024.

Interested men should contact our Clinical Trial Coordinator, Ms. Pamela Zehr, RN, MA at 319-353-8914; pamela-zehr@uiowa.edu.